B6 cont.

21. (Once Amended) A method according to claim 1, wherein the starter culture is used for inoculation of milk which is further processed to obtain a dairy product, which is selected from the group consisting of cheese, yogurt, butter, inoculated sweet milk and a liquid fermented milk product.

A marked version of the amended claims are attached hereto.

Please add claims 25 and 26 as follows.

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25. (New) A method according to claim 7 wherein the medium comprises one or more single milk components.

26. (New) The method of claim 25, wherein one or more single milk components include skimmed milk.

REMARKS

After amending the claims as set forth above, claims 1-26 are now pending in this application.

Applicant respectfully requests reconsideration of the present application in view of the foregoing amendments and in view of the reasons which follow.

First, Applicant believes the Examiner would enjoy the benefit of summary of the claimed invention. The claimed invention relates to a method of supplying a starter culture with a consistent quality i.e. consistent with respect to metabolic activity and cell density.

The starter culture is prepared according to the steps shown in example 1.2.1 of the specification.

Step A: Cells, Primary Inoculation Material (PIM) present, which may be in an ampoule, are inoculated in a volume of cultivation medium to obtain an inoculation material (IM).

Step B: The volume of step A is subsequently inoculated into a larger volume of cultivation medium which is incubated to obtain a primary fermentation material (PFM).

Step C: The volume of step B is used for inoculation of a still larger volume which is incubated to obtain a fermentation material (FM).

Step D: The cells are harvested from fermentation material (FM) obtained from step C by centrifugation to obtain a stock inoculation material (SIM).

The production, as described in step A-C, for providing the stock inoculation material (SIM) of the present invention is different from producing a starter culture using conventional methods, e.g. as described by Sing et al, in that conventional methods for providing a starter culture describes the transfer of the entire stock inoculation material (SIM) to a cultivation medium to produce the desired product. Whereas, the method of the claimed invention allows the stock inoculation material (SIM) to be divided into several fractions (subsets). Each of these fractions comprises the starter culture and may be used to inoculate a cultivation medium and produce the desired product.

Thus, in accordance with the claimed invention steps A-D are used for the preparation of the first stock inoculation material (SIM1). The following starter culture may be provided by the "one-step" procedure by direct inoculation of a subset (one fraction) of the produced first stock inoculation material (SIM1).

Contrary to this novel "one-step" method, conventional methods require providing starter cultures and propagating the cells using all the steps from A-D, and/or even more steps, for every starter culture provided.

The fraction of the stock inoculation material (SIM-x) of the claimed invention may either be used directly as a starter culture for the production of a desired product or the stock inoculation material (SIM-x) may be used for providing a further stock inoculation material (SIM-y) having the same consistent quality as the parental stock inoculation material (SIM-x)

One of the advantages of the present invention is that it is possible to provide a central production of a first stock inoculation material (SIM1). This first stock inoculation material (SIM1) is subsequently divided into several fractions, starter culture (SIM1a, SIM1b, SIM1c, etc.). Then the fractions may be transported to different

individual locations (production plants) to be used as a starter culture or for the production of additional stock inoculation material (SIM) and the distributed fractions of starter cultures sustain the same consistent quality for all the fractions at each of the different locations

Thus, due to the "one-step" procedure, compared to the "2 or more-step" procedures used in conventional methods (e.g. Sing et al.) it is possible to provide a starter culture of a consistent quality for direct inoculation and accordingly with a reduced risk of contamination, higher reproducibility, higher flexibility and with better quality management of the starter cultures.

With this description, Applicant addresses each of the Examiner's rejections.

Rejection of Claims 1-24 under 35 USC §112, second paragraph

Applicant believes that the clarification of the subject matter of the present invention will render the majority of the rejections under USC §112 irrelevant, as it appears from the comments below.

Claim 1

The Examiner rejects claim 1 as being vague and indefinite for reciting "with a consistent quality" and according to the Examiner the specification does not define the consistent quality. Applicant does not agree with this view. It is an essential and an inherent feature of a starter culture produced by a "one-step" method that the culture will be of a consistent quality. In the specification, the term is defined as a culture which will have a uniform performance quality, i.e. substantially same metabolic rate and substantially same number of cells pr ml.

The Examiner has also rejected claim 1 for reciting "use of, for subsequent production of starter culture, a subset" because it is unclear how this is a step for supplying a starter culture. Applicant believes that the amendment to claim 1 alleviates this rejection.

The Examiner furthermore rejects claim 1 for reciting "adjusted sufficiently in size". During the production of a starter culture the concentration of the culture before

harvest of the cells, step iv, will depend on the type of starter culture produced, composition of the medium etc. Accordingly, propagation of cells will go on for a period of time resulting in the concentration of relevance in the particular case. Thus, specific indications of time periods, number of cells, composition of propagation medium, and inoculation rates are not essential for carrying out the invention. The skilled person will easily determine these parameters once the principle of the invention, as described in claim 1, is submitted to the person of ordinary skill in the art.

Claim 2

The Examiner rejects claim 2 as being vague and indefinite because the specification and claim language fail to adequately define what quantities are "sufficient" to inoculate at least a 50,000 liter of cultivation medium. The rejection to claim 2 can be replied by using the same arguments as provided above. The person of skill in the art will know the quantity of the stock inoculum material (SIM) which are sufficient to inoculate at least 50,000 liters of cultivation medium. The information of relevance is that the method as described in claim 1 allows for production of a stock inoculum material (SIM) capable of inoculating, for example, a 50,000 liter industrial fermentor.

Claim 3

The Examiner rejects claim 3 for being indefinite for reciting 10^8 CFU per gram. The rejection to claim 3 as being indefinite is respectfully traversed by the Applicant. A starter culture is described by the number of cells (CFU) per g of the concentrate. As described above the relevant information provided to the person of skill in the art is that a starter culture of "normal concentration" (10^8 CFU per g) can be obtained by the method of the invention.

Claim 4

The Examiner rejects claim 3 for being vague and indefinite for reciting "at a rate of maximum 0.1%." Applicant respectfully traverses the rejection as put forward by the Examiner. A starter culture is always added at a specified rate to the cultivation

medium. The rate may be indicated as a percent of the total content of the cultivation medium.

Claim 5

The Examiner rejects claim 5 for being vague and indefinite because it is unclear what Applicant claims. Claim 5 has been amended and Applicant respectfully submits that the claim is now clear. The ratio as provided describes the ratio between the concentration of starter culture (CFU) in the stock inoculum material (SIM) and the cultivation medium immediately after inoculation.

Claim 7

The Examiner rejects claim 7 for being vague and indefinite because it is unclear what the medium contains. Claim 7 has been amended and Applicant respectfully submits that the claim is now clear.

Claims 8

The Examiner rejects claim 8 and its dependents as confusing because it is unclear how the subsets can be provided in liquid, frozen or dried form. In light of the description above and amendments to the claims, Applicant believes the Examiner will recognize that the stock inoculum material (SIM) can be obtained after step (iv) of claim 1, harvest of the propagated cells to provide a starter culture. We trust that the above description of the invention clarifies this point and that the Examiner will acknowledge the relevance of claim 8 as well as the claims depending therefrom.

Claims 9-11

The Examiner rejects claims 9-11 for including an "adding step" and for lack of antecedent basis for "the addition" in claim 9. Claims 9-11 have been amended to clarify the claims and provide antecedent basis, and Applicant respectfully submits that the claims are now clear.

Claim 12

The Examiner rejects claim 12 because "provided" lacks antecedent basis. Claim 12 has been amended to clarify the claims and provide antecedent basis.

Claim 16

The Examiner rejects claim 16 because "the container" and "the liquid" lack antecedent basis. Claim 16 has been amended to clarify the claims and provide antecedent basis.

Claim 17

Claim 17 has been amended, the basis for which can be found on page 10, line 32 of the description.

Claim 20

Claim 20 has been amended, the basis for which can be found on page 4, line 4-6.

Rejection under 35 U.S.C §102(e)

The Examiner has rejected claim 1, 3, 6, 17-22, and 24 under 35 U.S.C. §102(e) as being anticipated by Sing et al. (US 6146667). In response to this rejection, reference is made to the above discussion of the claimed invention and distinguishing the method as disclosed from conventional methods, including the method as disclosed in Sing et al. The novel and unobvious features of the claimed invention are distinctly described in the amended claim 1. The claim has been amended and the essential feature "one-step inoculation" has been added in the preamble of the claim and step (iv) has been further specified in order to clarify the invention and make explicit what was implicit in the claim. Consequently, the person of ordinary skill in the art, when reading amended claim 1, will immediately understand the invention by the guidance provided in the new claim. Accordingly, Applicant traverses the 35 U.S.C. § 102(e) rejection raised by the Examiner.

Sing et al. discloses a method for making a starter culture for inoculating milk to make a dairy product, the method comprises (a) introduction of a concentrated bacterial inoculum to a low solids growth medium and (b) ripening the inoculated medium for a period of time to produce a starter culture.

Accordingly, Sing et al. does not disclose a "one-step" procedure for the provision of a starter culture by using a subset of a stock inoculum material (SIM) for direct inoculation of a cultivation medium, where cells can be harvested from to produce a further stock inoculum material (SIM) which can be divided into several starter cultures (subsets). On the contrary, Sing et al. produces the starter culture in two steps and the entire starter culture is used for one subsequent inoculation.

Therefore, claim 1is not anticipated by Sing et al. Further, because all other claims depend from claim 1, these claims are not anticipated by Sing et al. as well. Thus, the present invention fulfils the requirements of 35 U.S.C. §102.

Rejection under 35 U.S.C §103(a)

The Examiner is correct in presuming that the subject matter of the various claims is commonly owned. Accordingly, there are no changes in inventor or invention dates of the claims.

The Examiner rejects claims 1, 2, 4, 11, 21, 22 and 24 under 35 U.S.C §103(a) as being unpatentable over Sing et al. (US 6146667). The present invention provides a method for producing a starter culture from a subset of a stock inoculation material (SIM). This produced subset of the stock inoculation material (SIM) may be used as a starter culture for direct inoculation of a cultivation medium without pre-propagation, pre-ripening, pre-activation or pre-cultivation of the starter culture cells. Alternatively, the subset can be used for further production of a stock inoculation material (SIM).

The present invention, when compared to conventional methods including the method described by Sing et al., also solves the problem associated with the risks of contamination and variations between separately produced batches of a starter culture. Furthermore, these improvements are obtained regardless of when or where the starter culture is produced and accordingly a consistent quality of the starter culture is

sustained. Because Sing et al. fails to solve or anticipate the problem of conventional methods which has been solved by the present invention, person skilled in the art would is not taught or motivated to provide the claimed invention. Therefore, claim 1 is not obvious in the light of the cited documents and the present invention fulfils the requirements of 35 U.S.C. §103.

Furthermore, the Examiner has made other unpatentable rejections under 35 U.S.C. §103, e.g., Claims 1 and 7 are rejected over Sing et al in view of Czulak et al. (US 4476143), Claims 1 and 8-10 are rejected over Sing et al. in view of Lizak (US 5952020), Claims 1 and 12-16 are rejected over Sing et al. in view of Vandenbergh et al. (US 6068774) and Matsumiya et al. (US 5225346), Claims 1 and 17-18 are rejected over Sing et al. in view of Czulak and Lizak, and Claims 1, 20, and 22-23 are rejected over Sing et al. in view of Rimler et al. (US 98523) and Lizak. Including Sing et al., none of the cited documents (Czulak et al., Lizak, Vandenbergh et al., Matsumiya at al. or Rimler et al.) solves or anticipates the problem of prior art methods which has been solved by the claimed invention. A person skilled in the art is not taught or motivated to provide the claimed invention by the teaching of any of the cited documents or any combination thereof. Therefore, claim 1 is not obvious in the light of the cited documents, as well as all the dependent therefrom. Thus, the present invention fulfils the requirements of 35 U.S.C. §103.

Conclusion

Applicant believes that the present application (Claims 1-26) are now in condition for allowance. Favorable reconsideration of the application as amended is respectfully requested.

The Examiner is invited to contact the undersigned by telephone if it is felt that a telephone interview would advance the prosecution of the present application.

Respectfully submitted,

Date April 18, 2002

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MARKED VERSION OF THE AMENDED CLAIMS

1. (Once Amended) A method for supply of a starter culture with a consistent quality **for one-step inoculation of a cultivation medium,** comprising the steps of:

(i) supply**ing**~~y of~~ a stock inoculum material comprising a concentrate of starter culture organism cells;

(ii) us**ing**~~e of, for subsequent production of starter cultures with a consistent quality,~~ a subset of said stock inoculum material for direct inoculation of a cultivation medium **for subsequent production of starter cultures with a consistent quality**~~with said subset of the starter culture organism~~;

(iii) propagati**ng** ~~on of the cells of~~ the starter culture organism **cells** for a period of time adjusted sufficiently in size to produce a desired amount of said cells; and

(iv) harvest**ing** ~~of~~ the propagated cells to provide ~~a~~**said stock inoculum material which subset thereof can be used as** ~~a~~**said** starter culture.

5. (Once Amended) A method according to claim 1, wherein the amount of the subset of the stock inoculum material for direct inoculation of the cultivation medium in step (ii) provides a ratio of the CFU per g of cultivation medium, immediately after inoculation, relative to the CFU per g of the subset of the stock inoculum material ~~to~~ be**ing** inoculated, said ratio being in the range from 1:100 to 1:100,000.

7. (Once Amended) A method according to claim 1, wherein the cultivation medium in step (ii) ~~does not substantially or entirely consist of whole milk but at least partially of skimmed milk or cream.~~ **may be any conventional medium used for propagation of microbial cells**.

9. (Once Amended) A method according to claim 8, wherein the frozen subset of the stock inoculum material is thawed before **direct inoculation of** the ~~addition to the~~ cultivation medium in step (ii).

10. (Once Amended) A method according to claim 8, wherein the subset of the stock inoculum material is combined with an aqueous medium to obtain a suspension of the cells before **direct inoculation of**~~adding it to~~ the cultivation medium in step (ii).

11. (Once Amended) A method according to claim 1, wherein the **direct inoculation of the cultivation medium** ~~subset of the stock inoculum material~~ in step (ii) is **provided** ~~added~~ under aseptical conditions or under substantially aseptical conditions ~~to the cultivation medium~~.

12. (Once Amended) A method according to claim 1, wherein the stock inoculum material is ~~provided~~ **supplied** in sealed enclosures.

16. (Once Amended) A method according to claim 12, wherein the sealed enclosures are ~~provided~~ **supplied** with -outlet means for connection of the enclosure to ~~the~~ **a**

container comprising the ~~liquid~~ cultivation medium, said outlet means permitting ~~the~~ concentrate of cells to be introduced ~~substantically~~ aseptically into the container to inoculate the ~~liquid~~ cultivation medium with said concentrate **of cells**.

17. (Once Amended) A method according to claim 1, wherein the starter culture organism in step (i) originates from a species selected from the group consisting of a lactic acid bacterial species, a *Bifidobacterium* species, a *Propionibacterium* species, a *Staphylococcus* species, a *Micrococcus* species, a *Bacillus* species, ~~an *Enterobacteriaceae* species including *E. coli*,~~ an *Actinomycetes* species, a *Corynebacterium* species, a *Brevibacterium* species, a *Pediococcus* species, a *Pseudomonas* species, a *Sphingomonas* species, a *Mycobacterium* species, a *Rhodococcus* species, **an *Enterobacteriaceae* species,** a fungal species and a yeast species.

20. (Once Amended) A method according to claim 1, wherein the starter culture is **a** ~~selected from~~**starter culture used in** ~~industries from~~ the ~~group consisting of the~~ food **industry**, feed **industry or**~~and~~ pharmaceutical industry.

21. (Once Amended) A method according to claim 1, wherein the starter culture is used for inoculation of milk which is further processed to obtain a dairy product, which is selected from the group consisting of cheese, yog~~h~~urt, butter, inoculated sweet milk and a liquid fermented milk product.